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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,203	01/29/2001	Sharron Gaynor Penn	AEOMICA-1	7320
7590 01/26/2006			EXAMINER	
Amersham Biosciences Corp			CLOW, LORI A	
Patent Department			ART UNIT	
800 Centennial Avenue			PAPER NUMBER	
P.O. Box 1327			1631	
Piscataway, NJ 08855			DATE MAILED: 01/26/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/774,203

Applicant(s)

PENN ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-67, 70-81 and 93-104 is/are pending in the application.
- 4a) Of the above claim(s) 15-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61-67, 70-81, and 93-104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

In view of the appeal brief filed on 21 October 2005, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claims 1-14 and 68-69 are cancelled. Claims 15-60 and 82-92 are withdrawn. Claims 61-67, 70-81, and 93-104 are hereby examined.

### **Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

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"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 61-67, 70-81, and 93-104 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility, for the reasons set forth in the Office Action of 29 January 2004.

Claims 61-67, 70-81, and 93-104 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### **Response to Applicant's Arguments**

1. Applicant argues that "the claimed microarrays have a well-established utility. Applicant asserts that the claimed invention relates to research tools not unlike those research tools listed by the Office, as clearly useful, in the most recent Manual of Patent Examining Procedure (MPEP)". Applicants cite the relevant section of the MPEP (2107.01). Applicant further submits that "the claimed microarrays clearly belong to such techniques as screening assays and nucleotide sequencing, and thus have clear, specific, and unquestionable utility".

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Applicants enclose a review article for support of their arguments. The review article is entitled "Microarrays:biotechnology's discovery platform for functions genomics" by Schena, M. et al. in *Trends in Biotechnology* (1998) Vol. 16(7), pages 301-306. Applicant points to a statement which says "advances in microarray technology enable massive parallel mining of biological data, with biological chips providing hybridization-based expression monitoring, polymorphism detection, and genotyping on a genomic scale". Although interesting scientifically, this does not provide a specific or substantial utility to the claimed generic invention. The instant claims do not recite expression monitoring of a specific gene or gene set, nor do they recite polymorphism detection, or genotyping. The uses in the prior art associated with the claimed microarrays do not impart utility to the claimed invention.

Applicant is reminded that a specific utility is *specific* to the subject matter claimed, as stated above. As such, the microarrays of the instant invention are not specific, as the asserted utility of the microarrays would require further research to confirm. The claimed microarrays are not supported by a specific asserted utility because the disclosed uses of these compositions are not specific and are generally applicable to any microarray. The research contemplated by applicant(s) to discover genes, does not constitute a specific and substantial utility. Potential uses for microarray high throughput or splice site identification do not provide an immediate benefit. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such microarrays. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the claimed microarrays such that another non-asserted utility would be well established for the microarrays.

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2. Applicant points to another reference entitled "DNA on a chip: serving up the genome for diagnostics and research" in *Molecular Medicine Today* (1997) Vol. 3(9), pages 384-389.

Applicant states that "the Wallace reference summarizes the industrial applicability/utility of the microarray platforms and that the well-established utility is one of a platform for high throughput gene and exon discovery, expression analysis of genes and alternative splicing analysis of exons, as well as identifying gene and exon expression patterns".

This is not persuasive. The claimed microarrays are not supported by a specific asserted utility because the disclosed uses of these compositions are not specific and are generally applicable to any microarray. The research contemplated by applicant(s) to discover genes, does not constitute a specific and substantial utility. Potential uses for microarray high throughput or splice site identification do not provide an immediate benefit. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such microarrays. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the claimed microarrays such that another non-asserted utility would be well established for the microarrays.

It is also noted that one of skill in the art would not know how to establish a meaningful result for non-specific single exon sequences, as contemplated herein. For example, if one fragment of a particular sequence were attached to the microarray in the instant invention and a researcher observed that upon exposure to a certain compound, expression were increased, how would one of skill in the art be able to determine if that increase were meaningful based upon the teachings in the specification? Other factors may have to be considered, such as type of

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compound, length of exposure etc... The specification provides no explanation of how to interpret results in a meaningful way such that the instant microarray would be useful as a research tool to analyze gene expression patterns. The specification only seems to indicate that the disclosed microarrays could be used in the discovery process, without providing any “real world context”.

3. Applicant argues that they have “used the methods and apparatus of the present invention to identify more than 15,000 exons in the human genomic sequence whose expression they have confirmed in at least one human tissue or cell type. Fully two-thirds of the exons belong to genes that were not at the time of our discovery represented in existing public expression databases, making the methods and apparatus of the present invention extremely powerful tools for novel gene discovery”.

This is not persuasive. The claimed microarrays are not even limited to be those from human genomic sequences. There is no claim to expression analysis or confirmation in human tissue or cell types.

#### **Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61-67, 70-81, and 93-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claims 61 and 102-104 recite a “single exon nucleic acid microarray comprising...said eukaryotic genome averaging at least one, two, three, and five introns per gene”, respectively. The specification fails to describe such a eukaryotic genome and therefore, there is no written description for such these limitations. The specification describes predicted exons, however, it fails to describe a genome with the claimed characteristics (page 33).

**Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61-67, 70-81 and 93-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 recites “said eukaryotic genome averaging at least one intron per gene”. It is unclear what limitation this imparts to the array. Clarification is requested.

Claims 62, 63, and 64 recite “probes include genomic sequence predicted to contribute to no more than one exon”. It is unclear what limitation is intended. Does this limit the probe or the genome? Clarification is requested.

Claim 70 recites “the microarray of claim 61, wherein each of said predicted exons”. This is unclear, as the microarray in claim 61 only includes a single exon. Does applicant intend that this limitation apply to the probe? Clarification is requested.



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Claim 80 recites "further comprising negative control probes". For what are the probes negative? This is unclear. Are they negative for an exon or some other sequence? Clarification is requested.

No claims are allowed.

### Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

January 23, 2006  
Lori A. Clow, Ph.D.  
Art Unit 1631

*Lori A. Clow*

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
1/23/06